MAR 1 5 2001

K010421

Summary of Safety and Effectiveness

Device Name:	Lorenz Fiducial Screw
Classification Name:	Stereotaxic Instrument and Accessory
Device Product Code:	Neurology: 84HAW (21 CFR 882.4560)

Intended Use:

The Lorenz Fiducial Screw is intended for establishing fixed reference point(s) in patients requiring stereotactic surgery. The Fiducial Screw can be used as an accessory with frameless navigation systems, as appropriate, from other manufacturers.

Description:

The Lorenz Fiducial Screw is a self drilling metallic fixation device with a stop used only as a reference point during stereotactic procedures.

Sterility Information:

The Fiducial screw will be marketed as non-sterile, single use devices. Steam Sterilization recommendations are included in the package insert and can be seen in Attachment I.

Substantial Equivalence:

Walter Lorenz considers the Lorenz Fiducial Screw equivalent to the Howmedica Leibinger, Inc. Ost-Reg Marker System for Stereotaxic Navigation, K961120 and Lorenz 1.0mm, 1.5mm, 2.0mm systems, K953385. **TAB 3** includes a substantial equivalence comparison table to competitive devices. **TAB 4** includes information for Howmedica Leibinger, Inc.

Possible risks:

Lorenz Fiducial Screws should not be used when there is the following:

1. Bone infection
2. Skin infection

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2001

Ms. Kim Reed
Regulatory Specialist
Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K010427
Trade Name: Lorenz Fiducial Screw
Regulatory Class: II
Product Code: HAW
Dated: February 6, 2001
Received: February 13, 2001

Dear Ms. Reed:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K010427

Device Name: Lorenz Fiducial Screw

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010427

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